In the Claims

1. **(currently amended)** A method of ~~preventing or~~ reducing diarrhea and/or steatorrhea in an HIV-positive patient comprising administering a High Activity Antiretroviral drug and a buffered and enteric coated composition comprising an enzyme or a cofactor selected from the group consisting of: pancreatic proteases, lipases, co-lipases, nucleases, amylases and other bio-active substances produced by the pancreatic gland in an effective amount to ~~prevent or~~ reduce diarrhea and/or steatorrhea.

2. **(currently amended)** A method of ~~preventing or~~ reducing diarrhea and/or steatorrhea in an HIV-positive patient associated with the treatment of with High Activity Antiretroviral drugs which comprise of protease inhibitors, nucleoside reverse transcriptase inhibitors, non-nucleoside reverse transcriptase inhibitors or a combination thereof, comprising the steps of:

a) administering to said HIV-positive patient a drug comprising a protease inhibitor, a nucleoside reverse transcriptase inhibitor, a non-nucleoside reverse transcriptase inhibitor, or a combination thereof contained in a pharmaceutically acceptable vehicle;

b) administering simultaneously or subsequently to said High Activity Antiretroviral drugs, a buffered and enteric-coated composition comprising:

of from about 10 to about 90% of an enzyme selected from the group consisting of pancreatic proteases, lipases, co-lipases, ~~co-enzymes~~ cofactor, nucleases, amylases and other bio-active substances produced by the pancreatic gland;

of from about 15 to about 60% of a buffering agent selected from the group consisting of: anhydrous sodium carbonate, sodium bicarbonate, potassium carbonate, potassium bicarbonate, ammonium carbonate, tromethamine, di(tris)hydroxymethyl-aminomethane carbonate, tris-glycine, di-arginine, tri-arginine, poly-arginine, di-lysine, tri-lysine, poly-lysine, diethylamine and triethanolamine, said buffering agent providing a pH of from 7 to 9 in the small intestine of a patient, and said lipase having an activity of from about 24% to about 100% at said pH of from 7 to 9;

of from about 0.5 to about 16% w/w of a disintegrant selected from the group consisting of ursodiol, starch, modified starches, microcrystalline cellulose and propylene glycol alginate;

of from about 1 to about 19% w/w of an adhesive polymer selected from the group consisting of polyvinylpyrrolidone, hydroxyethyl cellulose, cellulose acetate phthalate, ethyl cellulose and hydroxypropylmethyl cellulose; and

of from about 7 to about 15 % w/w of a non-porous, gastric acid-resistant and pharmaceutically acceptable polymer coating which contains less than 2% talc and which is insoluble in the pH range of from about 1.5 to about 5 but is soluble in the pH range of about 5.5 to about 9, said polymer coating comprises a polymer selected from the group consisting of hydroxypropyl methyl cellulose phthalate, cellulose acetate phthalate, diethyl phthalate, dibutyl phthalate, enteric coating polymer dispersion, and an acrylic based polymeric dispersion.

3. **(original)** The method of claim 2 wherein said protease inhibitor is selected from the group consisting of: indinavir sulfate, amprenavir, ritonavir, saquinavir, nelfinavir mesylate, and saquinavir mesylate.

4. **(original)** The method of claim 2 wherein said nucleoside reverse transcriptase inhibitor is selected form the group consisting of: zalcitabine, stavudine, zidovudine, lamivudine, lamivudine/zidovudine combo and didanosine.

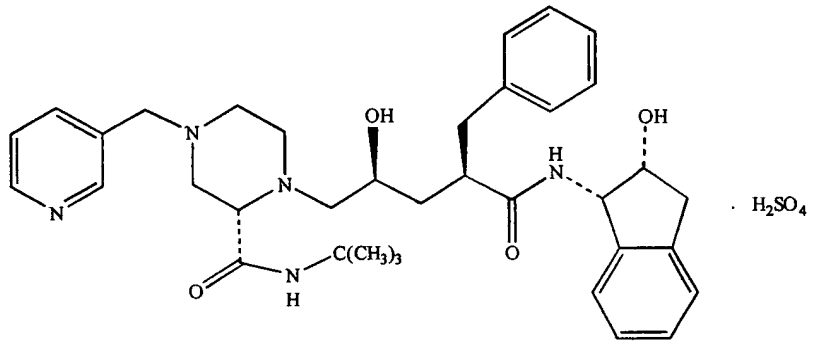
5. **(original)** The method of claim 2 wherein said non-nucleoside reverse transcriptase inhibitor is selected from the group consisting of: efavirenz, nevirapine, abacavir sulfate, and delavirdine mesylate.

6. **(currently amended)** The method of claim 2 wherein said bicarbonate-buffered and enteric-coated compositions comprising of from about 10 to 90% of an enzyme selected from the group

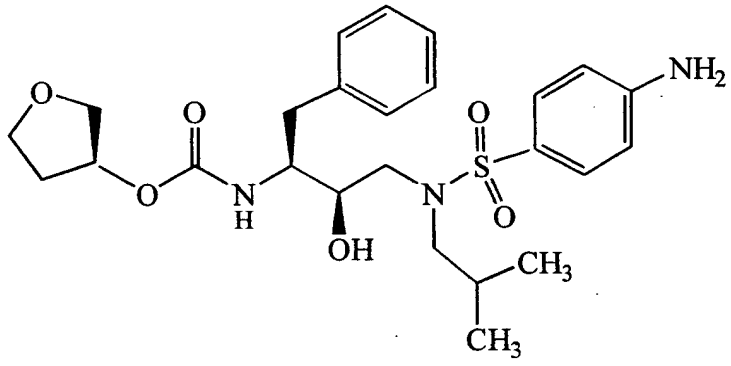
consisting of pancreatic proteases, lipases, ~~co-lipases~~ cofactors, nucleases, amylases and other bio-active substances produced by the pancreatic gland.

7. **(currently amended)** The method of claim 2 wherein said ~~co-enzyme~~ cofactor is a co-lipase.

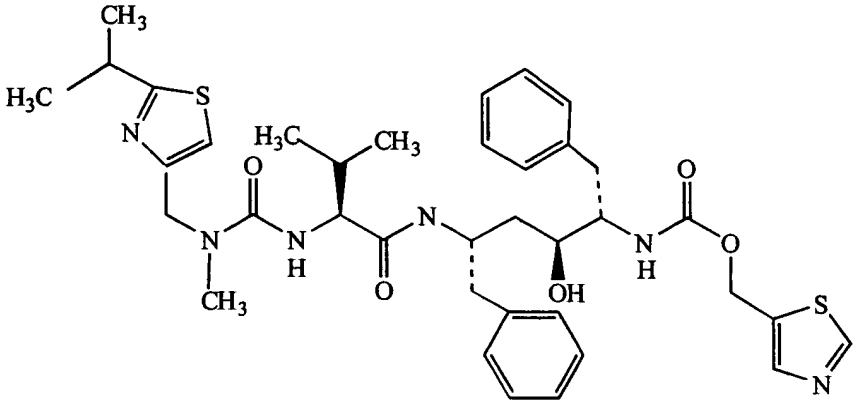
8. **(cancelled)** The method of claim 3 wherein said indinavir sulfate has the formula:



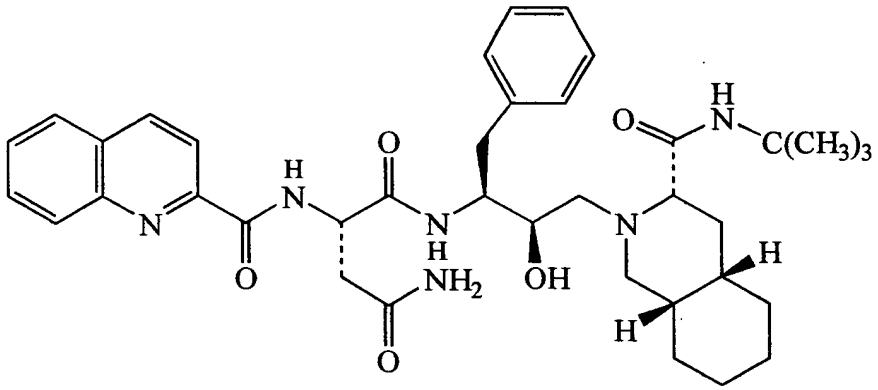
9. **(cancelled)** The method of claim 3 wherein said amprenavir has the formula:



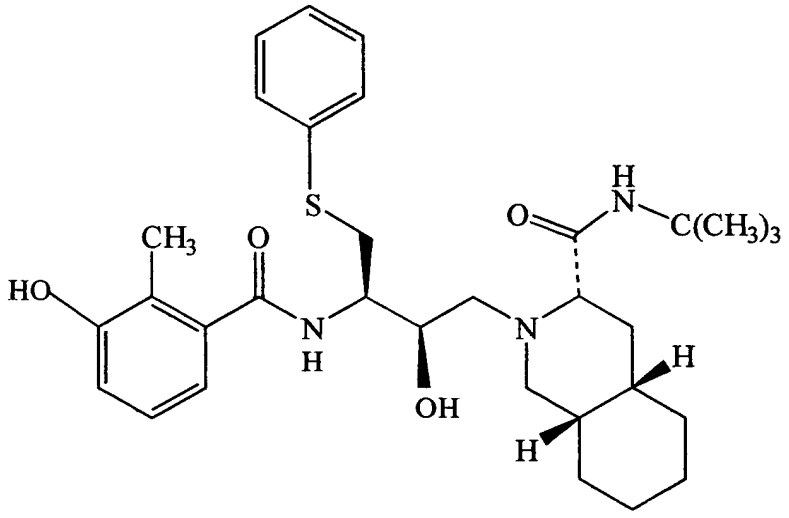
10. **(cancelled)** The method of claim 3 wherein said ritonavir has the formula:



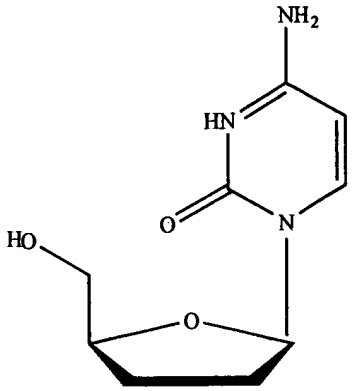
11. **(cancelled)** The method of claim 3 wherein said saquinavir has the formula:



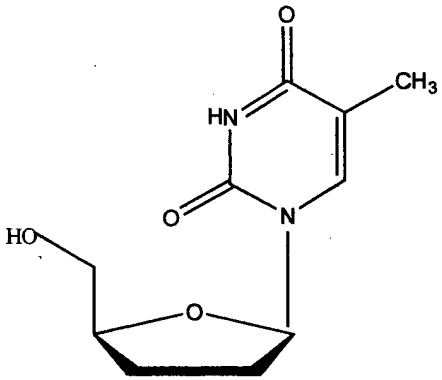
12. **(cancelled)** The method of claim 3 wherein said nelfinavir has the formula:



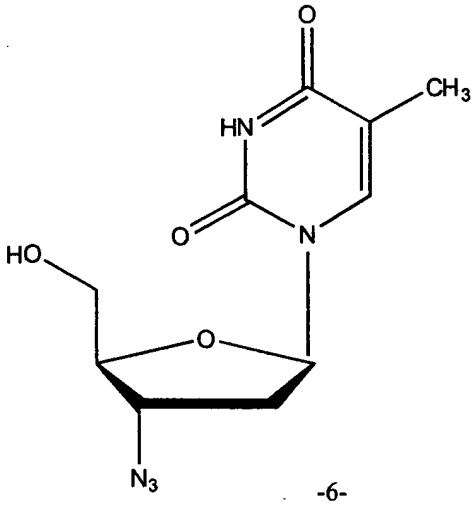
13. **(cancelled)** The method of claim 4 wherein said zalcitabine has the formula:



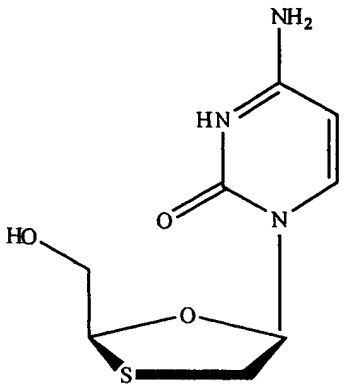
14. **(cancelled)** The method of claim 4 wherein said stavudine has the formula:



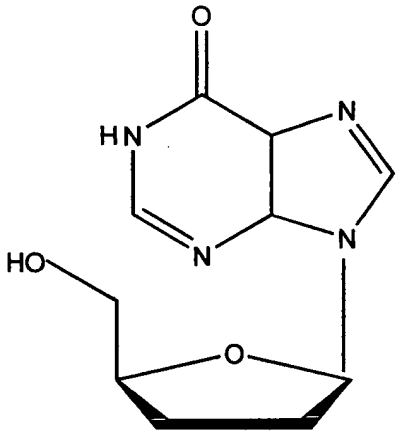
15. **(cancelled)** The method of claim 4 wherein said zidovudine has the formula:



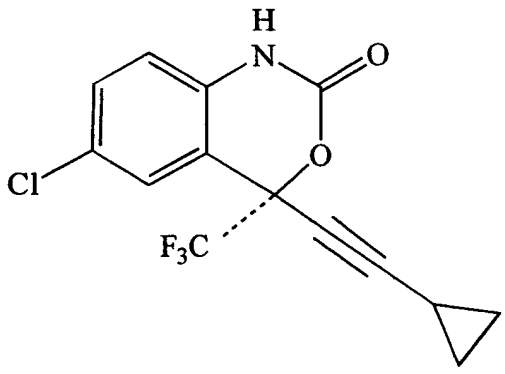
16. **(cancelled)** The method of claim 4 wherein said lamivudine has the formula



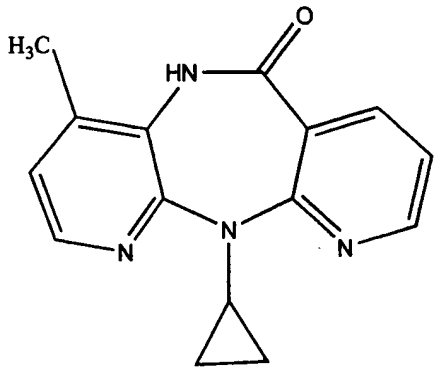
17. **(cancelled)** The method of claim 4 wherein didanosine has the formula:



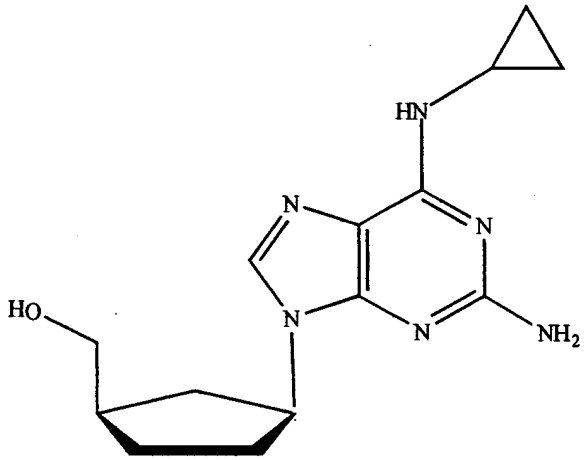
18. **(cancelled)** The method of claim 5 wherein said efavirenz has the formula:



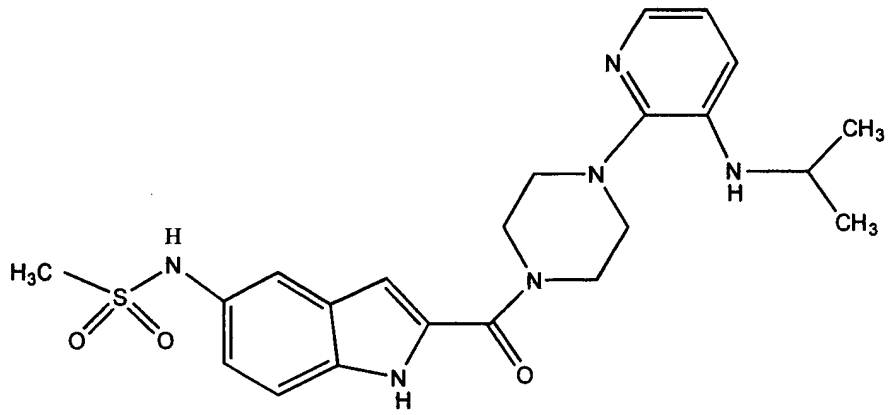
19. **(cancelled)** The method of claim 5 wherein said nevirapine has the formula:



20. **(cancelled)** The method of claim 5 wherein said abacavir has the formula:



21. **(cancelled)** The method of claim 5 wherein said delavirdine has the formula:



22. **(currently amended)** A composition for ~~preventing or~~ reducing diarrhea and/or steatorrhea in HIV-positive patients treated with High Activity Antiretroviral drugs comprising:

a protease inhibitor, a nucleoside reverse transcriptase inhibitor, a non-nucleoside reverse transcriptase inhibitor, or a combination thereof contained in a pharmaceutically acceptable vehicle;

a buffered and enteric-coated composition comprising:

of from about 10 to about 90% of an enzyme or a cofactor selected from the group consisting of pancreatic proteases, lipases, co-lipases, nucleases, amylases and other bio-active substances produced by the pancreatic gland;

of from about 15 to about 60% of a buffering agent selected from the group consisting of: anhydrous sodium carbonate, sodium bicarbonate, potassium carbonate, potassium bicarbonate, ammonium carbonate, tromethamine, di(tris)hydroxymethyl-aminomethane carbonate, tris-glycine, di-arginine, tri-arginine, poly-arginine, di-lysine, tri-lysine, poly-lysine, diethylamine and triethanolamine, said buffering agent providing a pH of from 7 to 9 in the small intestine of a patient, and said lipase having an activity of from about 24% to about 100% at said pH of from 7 to 9;

of from about 0.5 to about 16% w/w of a disintegrant selected from the group consisting of ursodiol, starch, modified starches, microcrystalline cellulose and propylene glycol alginate;

of from about 1 to about 19% w/w of an adhesive polymer selected from the group consisting of polyvinylpyrrolidone, hydroxyethyl cellulose, cellulose acetate phthalate, ethyl cellulose and hydroxypropylmethyl cellulose; and

of from about 7 to about 15% w/w of a non-porous, gastric acid-resistant and pharmaceutically acceptable polymer coating which contains less than 2% talc and which is insoluble in the pH range of from about 1.5 to about 5 but is soluble in the pH range of about 5.5 to about 9, said polymer coating comprises a polymer selected from the group consisting of hydroxypropyl methyl cellulose phthalate, cellulose acetate phthalate, diethyl phthalate, dibutyl phthalate, enteric coating polymer dispersion, and an acrylic based polymeric dispersion.

23. **(original)** The composition of claim 22 wherein said protease inhibitor is selected from the group consisting of: indinavir sulfate, amprenavir, ritonavir, saquinavir, nelfinavir mesylate, and saquinavir mesylate.

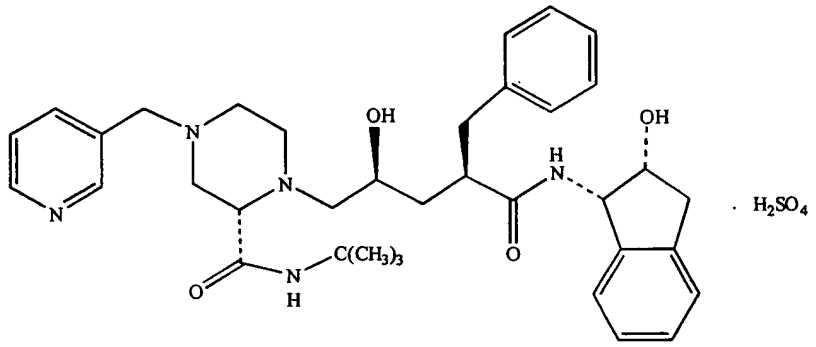
24. **(original)** The composition of claim 22 wherein said nucleoside reverse transcriptase inhibitor is selected form the group consisting of: zalcitabine, stavudine, zidovudine, lamivudine, lamivudine/zidovudine combo and didanosine.

25. **(original)** The composition of claim 22 wherein said non-nucleoside reverse transcriptase inhibitor is selected from the group consisting of: efavirenz, nevirapine, abacavir sulfate, and delavirdine mesylate.

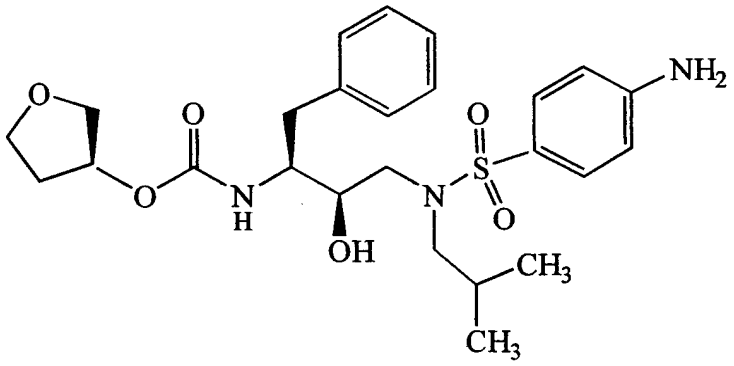
26. **(original)** The composition of claim 22 wherein said bicarbonate-buffered and enteric-coated compositions comprising of from about 10 to 90% of an enzyme selected from the group consisting of pancreatic proteases, lipases, co-lipases, nucleases, amylases and other bio-active substances produced by the pancreatic gland.

27. **(currently amended)** The composition of claim 22 wherein said ~~co-enzyme~~ cofactor is a co-lipase.

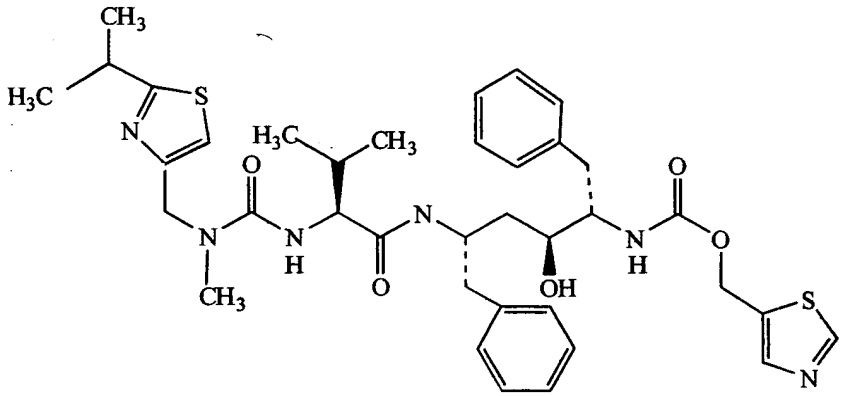
28. **(cancelled)** The composition of claim 23 wherein said indinavir sulfate has the formula:



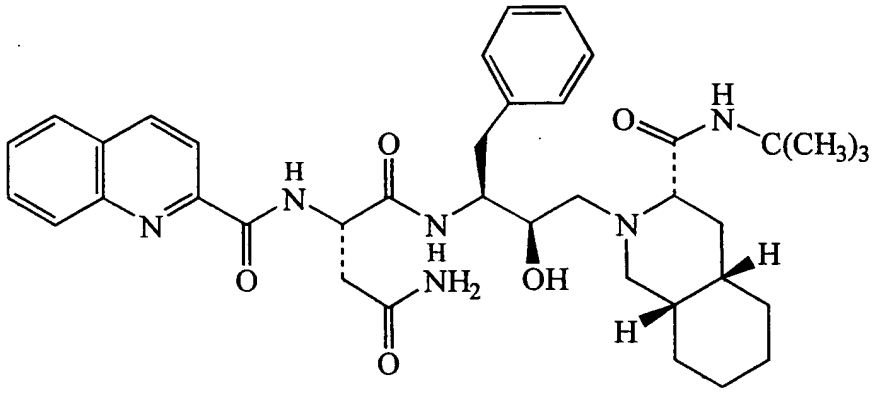
29. **(cancelled)** The composition of claim 23 wherein said amprenavir has the formula:



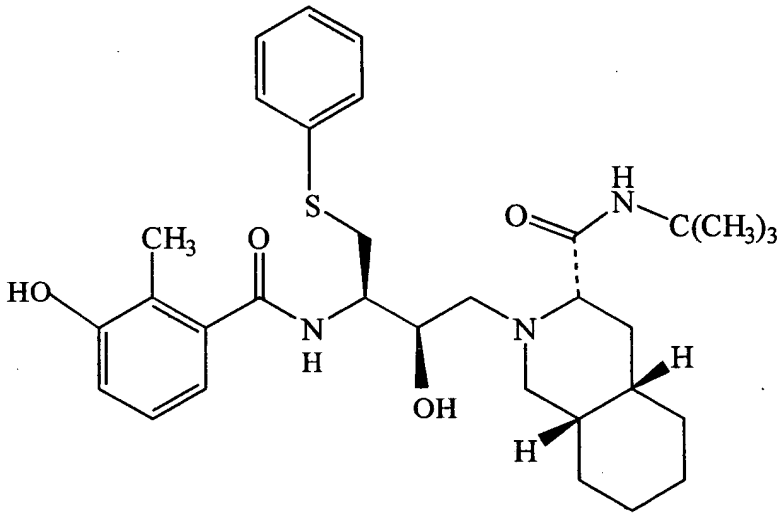
30. **(cancelled)** The composition of claim 23 wherein said ritonavir has the formula:



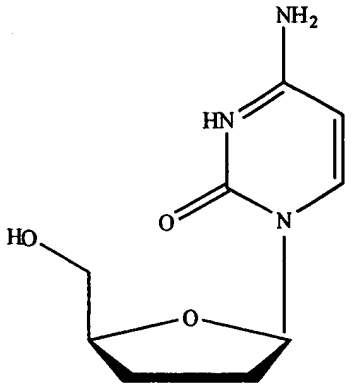
31. **(cancelled)** The composition of claim 23 wherein said saquinavir has the formula:



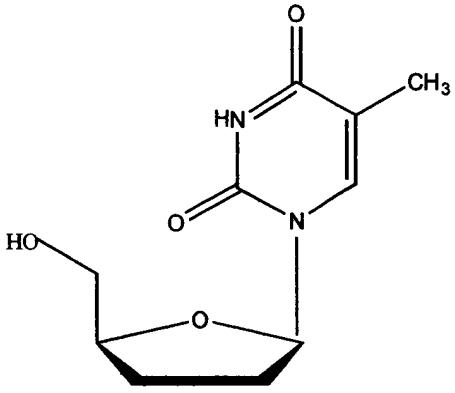
32. **(cancelled)** The composition of claim 23 wherein said nelfinavir has the formula:



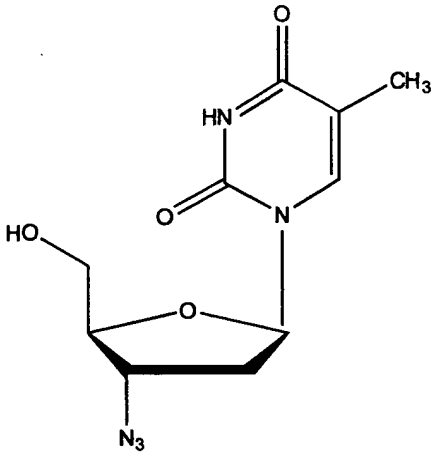
33. **(cancelled)** The composition of claim 24 wherein said zalcitabine has the formula:



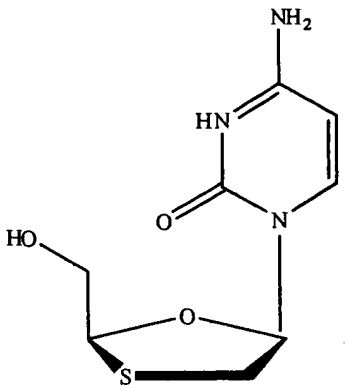
34. **(cancelled)** The composition of claim 24 wherein said stavudine has the formula:



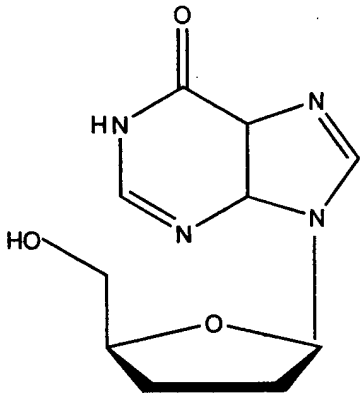
35. **(cancelled)** The composition of claim 24 wherein said zidovudine has the formula:



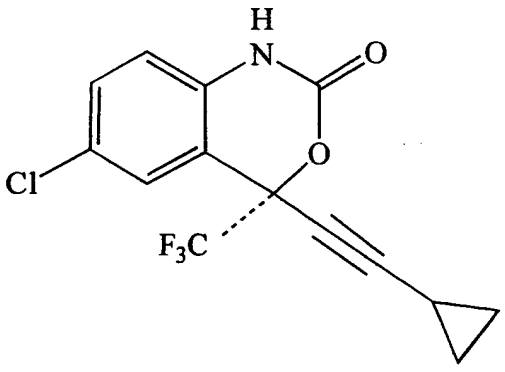
36. **(cancelled)** The composition of claim 24 wherein said lamivudine has the formula



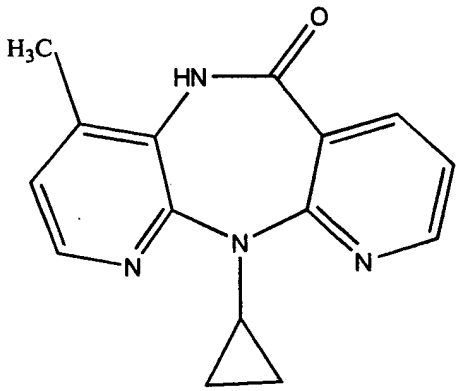
37. **(cancelled)** The composition of claim 24 wherein didanosine has the formula:



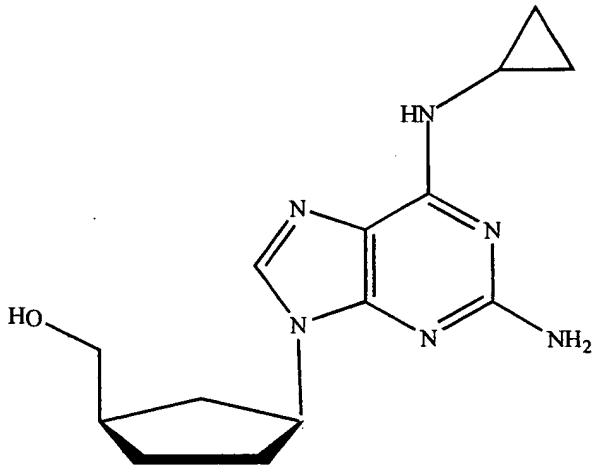
38. **(cancelled)** The composition of claim 25 wherein said efavirenz has the formula:



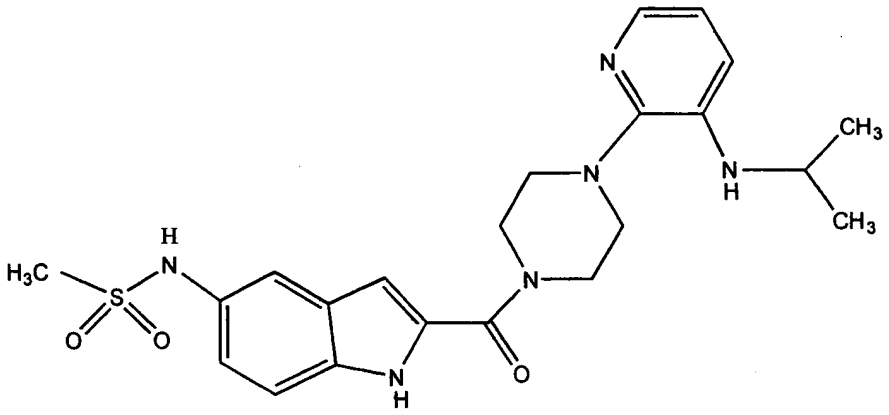
39. **(cancelled)** The composition of claim 25 wherein said nevirapine has the formula:



40. **(cancelled)** The composition of claim 25 wherein said abacavir has the formula:



41. **(cancelled)** The composition of claim 25 wherein said delavirdine has the formula:



42. **(currently amended)** A composition for ~~preventing or~~ reducing diarrhea and/or steatorrhea in HIV-positive patients treated with High Activity Antiretroviral drugs comprising:

a protease inhibitor, a nucleoside reverse transcriptase inhibitor, a non-nucleoside reverse transcriptase inhibitor, or a combination thereof contained in a pharmaceutically acceptable vehicle;

a buffered and enteric-coated composition comprising:

of from about 10 to about 90% of ~~co-lipase~~ cofactor produced by the pancreatic gland;

of from about 15 to about 60% of a buffering agent selected from the group consisting of: anhydrous sodium carbonate, sodium bicarbonate, potassium carbonate, potassium bicarbonate, ammonium carbonate, tromethamine, di(tris)hydroxymethyl-aminomethane carbonate, tris-glycine, di-arginine, tri-arginine, poly-arginine, di-lysine, tri-lysine, poly-lysine, diethylamine and triethanolamine, said buffering agent providing a pH of from 7 to 9 in the small intestine of a patient;

of from about 0.5 to about 16% w/w of a disintegrant selected from the group consisting of ursodiol, starch, modified starches, microcrystalline cellulose and propylene glycol alginate;

of from about 1 to about 19% w/w of an adhesive polymer selected from the group consisting of polyvinylpyrrolidone, hydroxyethyl cellulose, cellulose acetate phthalate, ethyl cellulose and hydroxypropylmethyl cellulose; and

of from about 7 to about 15% w/w of a non-porous, gastric acid-resistant and pharmaceutically acceptable polymer coating which contains less than 2% talc and which is insoluble in the pH range of from about 1.5 to about 5 but is soluble in the pH range of about 5.5 to about 9, said polymer coating comprises a polymer selected from the group consisting of hydroxypropyl methyl cellulose phthalate, cellulose acetate phthalate, diethyl phthalate, dibutyl phthalate, enteric coating polymer dispersion, and an acrylic based polymeric dispersion.

43. **(original)** A composition for correcting fat malabsorption and loss of body mass associated with diarrhea and/or steatorrhea in HIV-positive patients treated with High Activity Antiretroviral drugs comprising:

a protease inhibitor, a nucleoside reverse transcriptase inhibitor, a non-nucleoside reverse transcriptase inhibitor, or a combination thereof in a pharmaceuticlaly acceptabe vehicle;

a buffered and enteric-coated composition comprising:

of from about 10 to about 90% of co-lipase produced by the pancreatic gland;

of from about 15 to about 60% of a buffering agent selected from the group consisting of: anhydrous sodium carbonate, sodium bicarbonate, potassium carbonate, potassium bicarbonate, ammonium carbonate, tromethamine, di(tris)hydroxymethyl-aminomethane carbonate, tris-glycine, di-arginine, tri-arginine, poly-arginine, di-lysine, tri-lysine, poly-lysine, diethylamine and triethanolamine, said buffering agent providing a pH of from 7 to 9 in the small intestine of a patient;

of from about 0.5 to about 16% w/w of a disintegrant selected from the group consisting of ursodiol, starch, modified starches, microcrystalline cellulose and propylene glycol alginate;

of from about 1 to about 19% w/w of an adhesive polymer selected from the group consisting of polyvinylpyrrolidone, hydroxyethyl cellulose, cellulose acetate phthalate, ethyl cellulose and hydroxypropylmethyl cellulose; and

of from about 7 to about 15% w/w of a non-porous, gastric acid-resistant and pharmaceutically acceptable polymer coating which contains less than 2% talc and which is insoluble in the pH range of from about 1.5 to about 5 but is soluble in the pH range of about 5.5 to about 9, said polymer coating comprises a polymer selected from the group consisting of hydroxypropyl methyl cellulose phthalate, cellulose acetate phthalate, diethyl phthalate, dibutyl phthalate, enteric coating polymer dispersion, and an acrylic based polymeric dispersion.

44. **(original)** A method for correcting fat malabsorption and loss of body mass associated with diarrhea and/or steatorrhea in HIV-positive patients treated with High Activity Antiretroviral

drugs which comprise of protease inhibitors, nucleoside reverse transcriptase inhibitors, non-nucleoside reverse transcriptase inhibitors or a combination thereof, comprising the steps of:

a) administering to said HIV-positive patient a drug comprising a protease inhibitor, a nucleoside reverse transcriptase inhibitor, a non-nucleoside reverse transcriptase inhibitor, or a combination thereof contained in a pharmaceutically acceptable vehicle;

b) administering simultaneously or subsequently to said High Activity Antiretroviral drugs, a buffered and enteric-coated composition comprising:

of from about 10 to about 90% of an enzyme selected from the group consisting of pancreatic proteases, lipases, co-lipases, co-enzymes, nucleases, amylases and other bio-active substances produced by the pancreatic gland;

of from about 15 to about 60% of a buffering agent selected from the group consisting of: anhydrous sodium carbonate, sodium bicarbonate, potassium carbonate, potassium bicarbonate, ammonium carbonate, tromethamine, di(tris)hydroxymethyl-aminomethane carbonate, tris-glycine, di-arginine, tri-arginine, poly-arginine, di-lysine, tri-lysine, poly-lysine, diethylamine and triethanolamine, said buffering agent providing a pH of from 7 to 9 in the small intestine of a patient, and said lipase having an activity of from about 24% to about 100% at said pH of from 7 to 9;

of from about 0.5 to about 16% w/w of a disintegrant selected from the group consisting of ursodiol, starch, modified starches, microcrystalline cellulose and propylene glycol alginate;

of from about 1 to about 19% w/w of an adhesive polymer selected from the group consisting of polyvinylpyrrolidone, hydroxyethyl cellulose, cellulose acetate phthalate, ethyl cellulose and hydroxypropylmethyl cellulose; and

of from about 7 to about 15 % w/w of a non-porous, gastric acid-resistant and pharmaceutically acceptable polymer coating which contains less than 2% talc and which is insoluble in the pH range of from about 1.5 to about 5 but is soluble in the pH range of about 5.5 to about 9, said polymer coating comprises a polymer selected from the group consisting of hydroxypropyl methyl cellulose phthalate, cellulose acetate phthalate, diethyl phthalate,

dibutyl phthalate, enteric coating polymer dispersion, and an acrylic based polymeric dispersion.

45. **(original)** The method of claim 44 wherein said protease inhibitor is selected from the group consisting of: indinavir sulfate, amprenavir, ritonavir, saquinavir, nelfinavir mesylate, and saquinavir mesylate.

46. **(original)** The method of claim 44 wherein said nucleoside reverse transcriptase inhibitor is selected form the group consisting of: zalcitabine, stavudine, zidovudine, lamivudine, lamivudine/zidovudine combo and didanosine.

47. **(original)** The method of claim 44 wherein said non-nucleoside reverse transcriptase inhibitor is selected from the group consisting of: efavirenz, nevirapine, abacavir sulfate, and delavirdine mesylate.

48. **(original)** The method of claim 44 wherein said bicarbonate-buffered and enteric-coated compositions comprising of from about 10 to 90% of an enzyme selected from the group consisting of pancreatic proteases, lipases, co-lipases, nucleases, amylases and other bio-active substances produced by the pancreatic gland.